

REMARKS

Claims 1-21 are pending in this application. Claims 1, 5, 9 and 10 are amended herein for clarity to more particularly define the invention. Support for these amendments can be found in the language of the original claims and throughout the specification, at least, for example, in claim 10; and on page 9, first paragraph. Thus, it is believed that no new matter is added by these amendments and their entry and consideration are respectfully requested.

In the Action, the Examiner has requested that a species election be made among the following:

- 1) Vaccine against HAV, HBV, HCV, HDV, HVE or other entity; and
- 2) The type and nature of the expressed hepatitis or other heterologous antigen.

The Examiner alleges that these species lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.2. Specifically, the Examiner states that the central inventive concept is the expression of hepatitis antigens in eukaryotic cells and capable of expression and presentation in antigen presenting cells. The Examiner further states that this concept is neither novel or inventive because both Pugh et al. (J. Med. Virol. 20:229-246 (1986)) and Gough (J. Mol. Biol. 165:683-699 (1983)) prepared bacteriophage that comprise HBV gene products and further comprise an unmodified (native bacteriophage) surface.

Applicants provisionally elect **HBV** (target of the vaccine) expressing **HBsAg/HBeAg** and **INFA/β** (nature of the expressed antigen/heterologous proteins), with traverse. The traversal is on the basis that the Examiner has not demonstrated that the species do not relate to a single general inventive concept under PCT Rule 13.1. Claims 1 and 5 are amended herein to recite a hepatitis vaccine formulation comprising a bacteriophage particle the surface of which is unmodified and a pharmaceutically acceptable carrier therefor, the bacteriophage particle comprising a eukaryotic promoter and an exogenous nucleic acid molecule under control of the eukaryotic promoter and encoding a hepatitis virus polypeptide which is capable of expression and presentation on the surface of an antigen presenting cell of an organism, such that an immune response to said polypeptide is raised in the organism. Neither Pugh et al. nor Gough teach or suggest a bacteriophage particle comprising a eukaryotic promoter and an exogenous

nucleic acid molecule under control of the eukaryotic promoter and therefore the species identified by the Examiner form a invention form a single general inventive concept that indeed defines a contribution over the prior art and should be searched and examined together.

Therefore, applicants respectfully request reconsideration and withdrawal of this species election requirement, such that the search and examination of all of the embodiments of this invention can be carried out in the present application in the interest of efficient and compact prosecution of this application pursuant to USPTO Patent Business Goals (65 Fed. Reg. 54603, September 8, 2000).

Applicants wish to remind the Examiner that should this species election requirement be maintained, upon allowance of an elected species, applicants are entitled to consideration of additional species recited in these claims that are written in dependent form or otherwise include the limitations of an allowed claim.

The Examiner is encouraged to contact the undersigned directly if such contact will expedite the examination and allowance of the pending claims. No fee is believed due with this response. However, the Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,

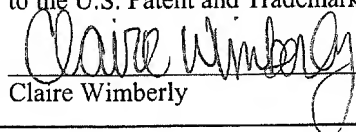


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I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on May 18, 2009.


Claire Wimberly